Medical Monomaterial Products with Functional IML Labels

Putting an End to Rejects

While in-mold labeling (IML) is standard for packaging products, it is still rarely used in the medical sector. Five renowned partners are working to change this. Their rationale is sound, because an initial model application has revealed both the added value that will accrue to the pharmaceutical industry and medical technology as well as a big plus in sustainability.

First things first: "The way the product has been manufactured up to now generates enormous opportunity costs. We're talking here about a reject rate of up to 10 %," says Johannes Strassner, CSO of Kebo AG, cutting straight to the point, when we meet up with him and four other members of a project group (**Fig. 1**) to talk about a new application for use in medical technology. Opportunity costs are the theoretical profit that companies lose out on if they fail to select the best option when faced with several alternatives.

The alternative developed by five partners – injection molding machine maker Arburg, toolmaker Kebo, automation specialist Beck Automation, label manufacturer MCC Verstraete, and Intravis, a leading supplier of optical inspection systems to the plastics packaging industry – concerns the production of centrifuge tubes. Billions of these plastic parts are used in the medical and pharmaceutical industries. So, there is a lot of money at stake. The main difference is that, before this, the graduated volume scale (**Title figure**) was printed on the tubes in a separate step after injection molding; the new process integrates this step through the use of in-mold labeling (IML).

Thanks to functional IML labels, the centrifuge tubes can have a filling scale and temperature-sensitive elements, for example. The latter use a color change to indicate when the cold chain has been breached. © Arburg

Abundant Advantages – for Sustainability, too

The line, which was first presented as a "proof of concept" at Fakuma 2023 where it met with a great response, will now be seen for the first time on the North American market at NPE 2024 (May 6 to 10, Orlando, FL/USA). IML combines many advantages, especially from a sustainability perspective. Strassner lists them: "The label indirectly adds stability to the tube, making it possible to reduce the wall thickness. That in turn allows manufacturers to slash the amount of plastic used in mass production. And, as the tube and the label are both made of PP, this mono-material product offers recycling potential."

He then adds the most important point, which is that additional error-prone working steps, such as printing and associated logistics, are eliminated. "Printing is a mechanical process that involves a wet medium. Reject rates of up to 10 % are the rule here, rather than the exception. The use of labels eliminates the problem of contamination with liquid paint. IML is simply clean and suitable for cleanrooms," says Strassner. Thanks to the new line, he adds, the entire production process is fast, space-saving, cost-efficient and without any additional hygiene risk. The result is greater output, a higher proportion of good parts and enormous flexibility, because IML makes it easy to switch from one design to the next.

Precision Permeates Every Step – Starting with the Label

The smooth running of the process requires a high level of precision on the part of all line components and »

Fig. 1. Project group with exhibit (from left): Sven Kitzlinger (Arburg), Johannes Strassner (Kebo), Kim Blondeel (MCC Verstraete), Ralf Ziemer (Beck Automation), Malte Westermann (Intravis). © Arburg

Fig. 2. A station with four adjustment heads ensures that labels are positioned exactly. © Arburg

production steps. This starts with the preliminary step of label production. Kim Blondeel, Sales & Business Development Manager Europe at MCC Verstraete, explains: "The labels are just 55 µm thick and are die-cut to a tolerance of just 0.2 mm. The tolerance for IML decorations for packaging products is usually 1 to 1.5 mm and the appearance and feel tend to be of secondary importance. But, for medical products, the labels must meet the technical and functional requirements in full." In addition to ruggedness and hygienic processing, aspects, such as small label size, the economics and the availability of large quantities, are also important. It should also be noted that the labels can be used in laboratories, because they are printed on the back, and that makes them alcohol-resistant and scratch-proof.

Such labels could also be conceivably used for other round parts, such as insulin pens and medical measuring cups. "When considering the potential of this technology, that would be the next logical step," confirms Strassner. However, the labels can also be equipped with other functions. Blondeel explains: "An additional heat-sensitive element allows users to see if the desired cooling temperature has been reached. In our latest application, the thermochromic color strip changes color reversibly at temperatures below 7 °C. But it would also be possible to implement different temperature setting and an irreversible color change."

Furthermore, an individual QR code on every label, for example, could carry additional information about recycling and warehouse management for the product. Blondeel also believes that RFID codes will in the future be able to track data on processes, quality and patients, with 100 % traceability for each individual part. For smooth digital communication between patient and doctor or for home-care applications, the data would have to be linked securely and intelligently, though.

Precise Label Positioning

As the scale on the tubes is supposed to indicate the exact filling level, precision handling and back-molding of the film inserts is essential. This is achieved by means of the automation supplied by Beck which ensures that the labels are positioned as precisely as possible in the cavities. Its label-adjustment head compensates for the production tolerance down to a few hundredths of a millimeter (**Fig. 2**). "This is essential for functionality and significantly reduces quality fluctuations and the number of rejects," says Ralf Ziemer, Sales Manager at Beck Automation AG.

The process cycle starts with the labels being removed from a magazine by a robot equipped with a 4-fold gripper. The technology for aligning and applying the labels then takes the precision to an exceptional level. "Each of the four adjustment heads measures a separate label. For this, each label is moved on two axes and at one angle. The outcome is an absolutely positionally accurate mapping of the cavities, which is monitored by a camera system supplied by Intravis," says Ziemer. The labels are subsequently electrostatically charged to stop them slipping. A second robot, also fitted with a 4-fold gripper, then picks them up and places them with precision on the insertion cores (**Fig. 3**). To load all eight cavities of the mold, the robots perform this operation twice in each cycle. "Given that the cycle time is approx. 10 s, this can be done readily," adds Ziemer.

Production Cell Fits into Predefined Production Grids

An 8-cavity mold from Kebo with valve-gate hot runner is used to produce ready-to-use 15 milliliter PP tubes. Positional accuracy is guaranteed here as well. "A flow edge on the component contributes to this by directing the melt into the cavity at a favorable flow angle," explains Strassner. In addition, the servo-electric drives of the injection molding machine ensure precise and reprodu-

Info

The process is currently in the validation phase. Further information on the project partners:
www.arburg.com/en
www.beck-automation.com/en
www.intravis.com
iml.mcclabel.com/en
www.kebo.com/en

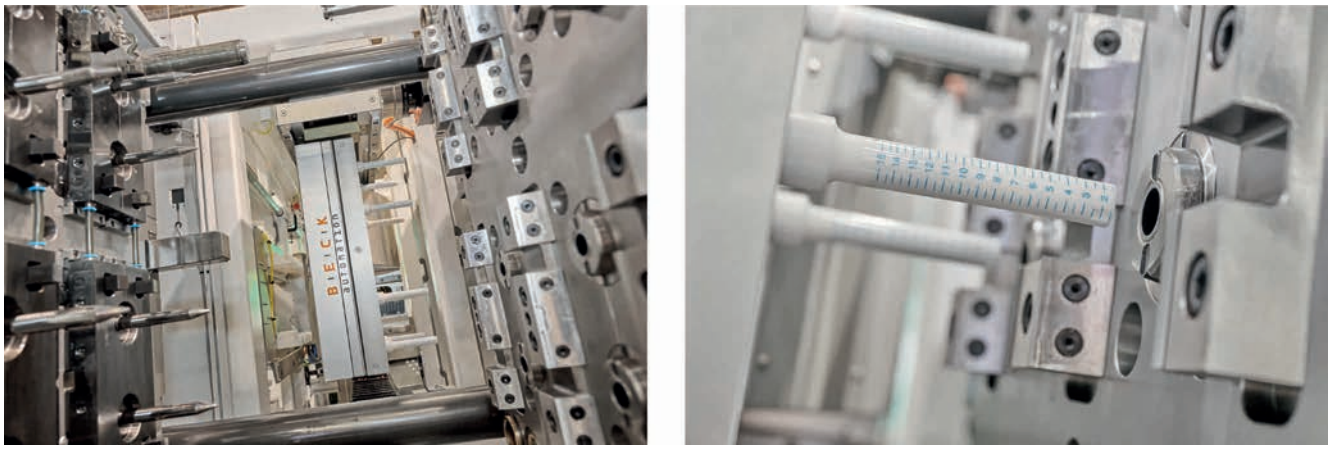

Fig. 3. The handling system moves into the mold (left) to place the labels in the eight cavities. Maximum precision is required to ensure that the scale reliably fulfills its purpose in the intended application. © Arburg

cible mold positioning. A further criterion for moldmakers is that, on account of the low wall thickness, the mold cores must exhibit high rigidity to achieve centric filling and minimize core misalignment.

Sustainability is also served by the cell's compact footprint. "The production cell's footprint easily fits into predefined production grids," says Sven Kitzlinger, medical technology expert at Arburg GmbH + Co KG. The centerpiece is an Allrounder 520 A Ultimate electric injection molding machine with a clamping force of 1500 kN, which is designed for fast, demanding processes, such as thin-wall applications. This high-performance machine in cleanroom design meets the requirements of class ISO 7. According to Kitzlinger, the temperature of the direct drives is liquid-controlled, and special, food-compatible NSF-H1-rated lubricants are used.

Real-Time Optical Inspection of Molded Parts

After injection molding and removal from the mold, the parts are inspected in real time (**Fig. 4**). This is done by four cameras (type: IMLWatcher) from Intravis that are integrated into the automation system. "They check that the scale is in the right place or whether an arbitrary injection molding error, such as thread pulling, has occurred on the sprue. Small inaccuracies, especially in the positioning of the labels, can have a major impact here," stresses Malte Westermann, International Sales Manager at Intravis GmbH. The checks also include the tube neck and thread as well as recognizing the print-to-cut offset.

If a faulty part is detected, the inspection unit sends a signal directly back to the automation system so that the part in question can be ejected. The IMLWatcher control panel also displays the type of error that has occurred. This enables the production staff to immediately decide if intervention is needed. Compared with the classic combination of production and downstream printing, the line is in a good place: "This is a very mature technology, the reject rate has been less than 1 % right from the start," says Westermann. The focus now is on process validation. In a real application, the production cell could also be used to screw the tubes together and pack them in flow bags.

What's next? Johannes Strassner replies: "We get a lot of inquiries, but in the medical/pharma sector you need time and patience. In any event, we have the rationale and positive experience on our side." And what about the project consortium? "There's a lot to be said for continuing to work together, because the more projects we complete together, the better we become." ■

Dr. Clemens Doriat, editor

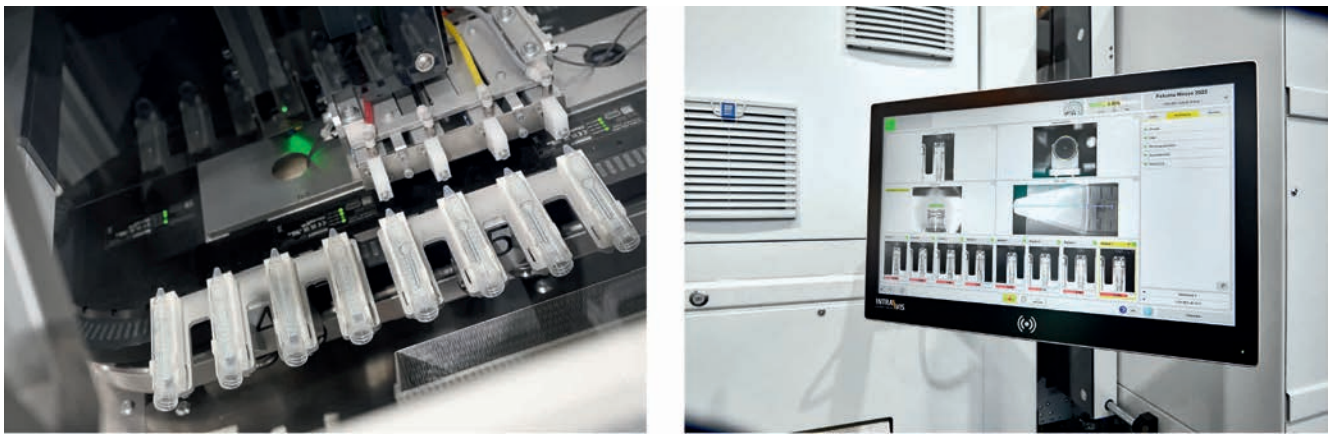

Fig. 4. The IMLWatcher is a complete solution for optical inspection of molded parts. The hardware is combined with software that is designed exclusively to detect IML-specific defects. © Arburg